510(k) Summary

SUBMITTED BY

Doug McWhorter
Olsen Medical
3001 W Kentucky Street
Louisville, KY 40211

Date Submitted: July 20, 2004

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade/Proprietary Name:	Olsen Medical Anterior Cervical Vertebrae Plate System
Common/Usual Name:	Cervical Plating Instrumentation
Device Product Code:	KWQ
Classification:	888.3060
Classification Name:	Spinal Intervertebral Body Fixation Orthosis

PREDICATE DEVICE

Synthes CSKP Variable Angle Cervical Plate Locking System (K031276)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92

DEVICE DESCRIPTION AND MATERIALS OF CONSTRUCTION

The Olsen Medical Anterior Cervical Vertebrae Plate System consists of plates and locking screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2 to C7).

The Olsen Medical Dynamic and Semiconstrained Plate Systems each come in lengths ranging from 23mm to 109mm. All of the plates, regardless of the length, are 16mm and 19mm wide at the cephalad and caudal ends of the plate, respectively. The Dynamic Plates have slots to receive the screws and the Semiconstrained Plates have round holes to receive the screws. All other plate dimensions are the same. Both plates each have tack holes and drill guide holes at the cephalad and caudal ends of the plate. Both plates are curved both in the longitudinal and lateral planes.

The implants of these systems are manufactured from medical grade titanium alloy Ti6 Al4 V meeting the requirements of ASTM F136 or ASTM 1472.

INDICATIONS FOR USE

The Olsen Medical Dynamic and Semiconstrained Plates are intended for anterior screw fixation of the cervical spine (C2 to C7) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc, confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis and tumors (primary and metastatic), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), pseudoarthrosis and failed previous fusions.

PERFORMANCE DATA

Testing for substantial equivalence to the Synthes CSPL Variable Angle device is done per ASTM 1717 in accordance with FDA Guidance for Spinal System 510(k)s, May 3, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2005

Mr. Larry D. Potts
Olsen Medical
3001 West Kentucky Street
Louisville, Kentucky 40211

Re: K042073
Trade/Device Name: Anterior Cervical Vertebrae Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 13, 2004
Received: January 13, 2004

Dear Mr. Potts:

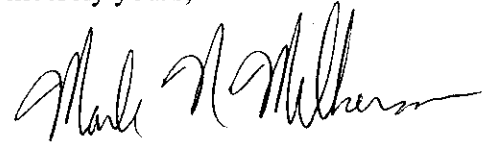
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): **K042073**

Device Name: **Olsen Medical Anterior Cervical Vertebrae Plate System**

Indications For Use: The *Olsen Medical Dynamic and Semiconstrained Plates* are intended for anterior screw fixation of the cervical spine (C2 to C7) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis and tumors (primary and metastatic), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), pseudoarthrosis and failed previous fusions.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042073